Documentation
21 CFR Part 1271

Martha A. Wells, MPH, RAC
Acting Branch Chief
Division of Human Tissues
OCTGT

Feb. 1, 2005 - Dallas

Focus: Documentation of:

- Procedures: 1271 .180 and 1271.47
- Records: 1271.270 and 1271.55
- Tracking: 1271.290
- Complaint Files: 1271.320

Note: These are not Core Current Good Tissue Practices (CGTPs)!!

Why are There 2 Procedures and Records Sections??

- Procedures and records requirements in
  - CGTP
  - Donor Eligibility (DE)
- CGTP requirements not being implemented for reproductive establishments at this time
- Need procedures and records requirements in the DE section for reproductive establishments to comply with by May 25, 2005
- FDA encourages reproductive establishments to implement voluntary compliance with all CGTPs

Procedures/SOPs for What??

- Anything related core CGTPs and the HCT/P for preventing the introduction, transmission, or spread of communicable disease!!
- FDA focus to date has been on donor eligibility
- Recovery to distribution
- Reporting
- Tracking
- ? FDA inspection – not required but helpful

Procedures/SOPs: 1271.180

- Establish and maintain procedures appropriate to meet core CGTP requirements
- Review and approve before implementing
- Readily available to personnel in the area where these functions are performed, or nearby area
- Can adopt current standards from another organization, if you verify that they meet these minimum requirements and are appropriate for operations performed

Procedures/SOPs: 1271.47

- Establish and maintain procedures for all steps that you perform in testing, screening, determining donor eligibility, and complying with all other requirements of Subpart C – Donor Eligibility
- Review and approve before implementing
- Availability to personnel
- Departures from procedures
- Adopting standard procedures

Procedures/SOPs

- Establish and Maintain means
  - Define, document (in writing or electronically), and implement
  - Follow, review, and as needed, revise on an on-going basis
  - Design to ensure compliance with the requirements
- Review and approve
  - Before implementing
  - By a responsible person

Procedures/SOPs

- Make available to personnel
  - In the area where operations are related
  - Or in a nearby area if impractical
- Departures from procedures
  - Record and justify if relevant to preventing risks of communicable disease transmission at the time of its occurrence
  - Can’t release HCT/P for distribution until determination that the departure did not increase communicable disease risks

Procedures/SOPs

- Adopting standard procedures
  - Professional associations technical manual -example
  - Verify that the procedures are consistent with and at least as stringent as requirements
  - Are appropriate for your operation
  - Are being followed exactly in your operation

Other Procedures/SOPs

- Some procedure requirements are found in other sections of the CGTPs such as:
- 1271.160 Quality Program
  - Documenting and reviewing
  - Approval and revision
- 1271.265 Receipt, pre-distribution shipment, and distribution
  - For all activities including release criteria
  - Return to inventory

Other Procedures/SOPs

- 1271.190 Facilities
  - For cleaning and sanitation
  - To prevent the introduction, transmission, or spread of communicable disease
  - Must assign responsibility for sanitation
  - Sufficient detail of methods used and schedule
- 1271.200 Equipment – similar provisions as above

Examples of Important Procedures not Detailed in 1271

- Recovery – Core CGTP need to address:
  - Time between death and recovery
  - Delays in refrigeration
- Archiving obsolete procedures not required but is encouraged
  - Important as reference for HCT/Ps still available and in storage

Records: 1271.270 -CGTPs

- Maintain records concurrently with the performance of each step
- Records must be
  - Accurate
  - Indelible
  - Legible
- Records must
  - Identify the person performing the work
  - Dates the work was performed
  - Provide a complete history of the work performed

Records: CGTP

- Have a records management system relating to core CGTP requirements
  - Records of each HCT/P's history and manufacture,
  - Include labeling and packaging procedures, equipment logs
- Maintain original paper records or copies; records maintained electronically must be backed up

Records: CGTP

- Retain records for 10 years after date of administration of HCT/P, or
- If date of administration is not known, 10 years after date of distribution, disposition, or expiration, or
- Whichever is latest
- Keep records of contracts and agreements with other establishments

Donor Eligibility Records Accompanying the HCT/P: 1271.55

- Distinct identification code affixed to the container that has no personal identifiers unless for autologous or directed reproductive donation
- Statement whether donor has been determined to be eligible or ineligible
- Summary of the records used to make the donor eligibility determination
- No records with personal information that might identify the donor

Summary of Records: 1271.55

- Statement that communicable disease testing performed by CLIA certified lab or with equivalent status as determined by the Centers for Medicare and Medicaid
- Listing and interpretation of the results of all communicable disease tests
- Name and address of the establishment that made donor eligibility determination
- If HCT/P donor ineligible based on screening
  - Note the reason for the determination
  - Assists physician in assessing risks

Specific Requirements for DE Record Retention

- Results and interpretation of all testing for relevant communicable disease agents including name and address of testing labs
- Name of the responsible person who made the determination and the date
- Accurate, indelible and legible –same as 1271.270
- Relevant medical records and information on the donor's identity must be in English

Specific Requirements for DE Record Retention

- If records translated to English- statement of authenticity by the translator
- Non –English original records must be retained
- Records available for FDA inspection or upon request from FDA
- Readily retrieved from another location by electronic means – OK
- 10 year retention – same as 1271.270

Records: Other

- 1271.155 Documentation that exemption has been granted
- 1271.160 Documentation of corrective actions
- 1271.190 Facilities – of cleaning – retain for 3 years
- 1271.200 Equipment- maintenance, cleaning, sanitizing, calibration etc.
  - Recent records must be displayed on or near each piece of equipment or
  - Readily available to those performing activity

Records: Others

- 1271.210 Supplies and reagents
  - Receipt
  - Verification
  - Identifying lots used for each HCT/P
- Provision for keeping records in the event that an establishment goes out of business
  - Not required
  - Encouraged especially for HCT/Ps that may be stored indefinitively and difficult to replace
  - Such as cord blood and embryos

Tracking: 1271.290

- If you perform any step in manufacture in which you handle the HCT/P
- You must track it to facilitate investigation of actual or suspected communicable disease transmission
- Have a system that enables tracking of all HCT/Ps
  - From donor to consignee or final disposition
  - Vice versa
  - List of consignees
  - Disposition of each HCT/P

Tracking

- Inform consignee in writing of these requirements and your tracking system
- Each HCT/P must have a distinct identification code (ID) that relates the HCT/P to the donor and all records
- Labeling that includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient, vice versa

Tracking

- Distinct ID code must not include
  - An individual's name
  - Social Security number, or
  - Medical record number (except for autologous or directed donations)
- You may use the code assigned by another establishment, but if you assign a new code, relate it to the old one

Tracking

- Consignee can be
  - Hospital receiving the HCT/P
  - Surgeon who uses the HCT/P
- FDA can’t mandate hospitals to comply
- Tracking to consignee – similar to professional association voluntary standards such as AATB and EBAA
- Donor and patient information not restricted by HIPAA
  - Establishment not a covered entity
  - Can share de-identified health information

Example of Successful Tracking System

- Establishment provides hospitals with
  - Peeloff labels with unique product identifier and name of bank providing HCT/P
  - Tracking logs to use to control inventory
- Hospital returns self-addressed envelope with information on use of HCT/P
- Establishment sends regular reminders to hospital
- 85 to 100 percent compliance

What is a Complaint?

- Any written, oral, or electronic communication about a distributed HCT/P that alleges
  - That an HCT/P has or may have transmitted a communicable disease to the recipient or
  - Any other problem with an HCT/P relating to the potential for transmission -
  - Related to failure to comply with current good tissue practice

Complaint Files: 1271.320

- Establish/maintain complaint file and procedures for
  - Review
  - Evaluation
  - Documentation complaints
  - Related to core CGTP requirements
- Files must be available for FDA review and copying upon request
- FDA treats all donor/patient information as confidential

Complaint Files

- Determine if it is a deviation or adverse reaction, and if it needs to be reported to FDA
- Review report as soon as possible in case an investigation is needed so as to meet the time requirements for reporting
- Adverse reaction reports – within 15 calendar days of initial receipt of the information
- HCT/P deviation reports – within 45 days of discovery of the event

Complaint Files

- Determine whether an investigation is necessary or not
- Document reason and name of individual responsible for the decision
- Determine whether this is an isolated event or represents a trend
- Determine if the complaint should be referred to another establishment that performed the manufacturing step